

Claims 14-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hiji, U.S. Patent 4,912,089 or, Claims 14 and 17-19 and 21 over Shanmugasundaram et al. (AR). Claims 14, 19, 21 and 23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hiji '089 alone for Claims 14-17 or Shanmugasundaram et al (AR) further in view of Womack, U.S. Patent 5,730,988 for Claims 14-19, 21 and 23. These rejections are respectfully traversed.

Hiji '089 discloses that *Gymnema sylvestre* inhibits the production of a glucan that adheres to surfaces of teeth to form bacterial plaque. The *Gymnema sylvestre* and, particularly, gymnemic acid derived from *Gymnema sylvestre*, appears to be the active agent that inhibits the formation of plaque on tooth surfaces. The desired extract is prepared by immersing dried leaves in warm water to produce a warm water extraction solution. If an alcohol were used, certain chlorophyll, lipid and other substances would be eluted; warm water is used to avoid extraction of these substances. (See Hiji, Col. 2, lines 33-36.) The warm water extract is acidified to precipitate gymnemic acid. Hiji '089 discloses, in Assay Example III, results indicating that an "extract" from the coarse tea (presumably described in Example II) inhibits an increase in blood sugar compared to other types of teas. Applicants note that the preparation of teas is very different from the preparation of extracts described earlier in the patent. Teas are produced by drying leaves of *Gymnema sylvestre* and subsequently roasting them. Alternatively, green teas are prepared by steaming fresh leaves of *Gymnema sylvestre* and then rumpling and drying the leaves. The teas do not use an "extract" of the type previously described.

Applicants' claims involve the administration of a composition isolated from the leaves of *Gymnema sylvestre* using a specific extraction technique involving, among other steps, steeping leaves in an aqueous solution comprising **one or more high polarity solvents**. The high polarity solvent may be selected from methanol, propanol, butanol, and amyl alcohol, and a combination of at least two such solvents is preferred. (See applicants' specification at page 6, lines 17 – 25.) Hiji '089 expressly teaches **against** the use of alcohols. (See Hiji Col. 2, lines 33-36.) The extracts used by Hiji and the applicants are thus fundamentally different. Furthermore, Hiji '089 discloses results relating to inhibiting an increase in blood sugar by administering a coarse tea made from *Gymnema sylvestre*. Hiji does not state or suggest that

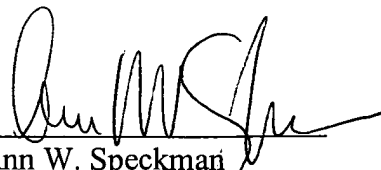
such compositions may be useful for treating diabetic patients, for treating impaired glucose tolerance, for regenerating the pancreatic islets of Langerhans, for regenerating the pancreatic beta cells, for increasing endogenous insulin levels or for increasing the production of proinsulin in a patient. It is therefore urged that applicants' claims are not anticipated by or obvious in view of Hiji '089.

The Shanmugasundaram et al. (AR) reference discloses the effects of certain preparations of *Gymnema sylvestre*. The leaves of *Gymnema sylvestre* were air dried, ground into powder in a hand operated coffee grinder and stored in glass stoppered bottles for administration and tests. Applicants do not find any suggestion in this reference of an extraction technique involving the use of one or more high polarity organic solvents, or any other extraction technique, which would significantly alter the composition of the extract. Womack '988 discloses a nutritional supplement for improving glucose tolerance. The nutritional supplement includes a Phase I vanadate and chromium supplement in combination with a Phase II supplement comprising *Gymnema sylvestre* and lipoic acid. Water soluble extracts of *Gymnema sylvestre* were used. The '988 patent indicates that it is believed that *Gymnema sylvestre* appears to enhance endogenous insulin, possibly by regeneration/revitalization of residual beta cells in the endocrine pancreas. The inventors also note that daily supplementation with *Gymnema sylvestre* has been shown to cause a significant reduction in blood glucose, glycosylated hemoglobin and glycosylated plasma proteins, thereby allowing conventional drug dosages to be decreased.

Applicants do not perceive any combination of the prior art teachings relied upon for rejection that anticipates or renders the claims obvious. In particular, applicants note that methods for treating diabetic patients are distinct from methods for treating impaired glucose tolerance, are distinct from methods for increasing the production of proinsulin in a patient. Applicants do not discern any teaching, or any combination of teachings in the prior art cited that would suggest that the extract of *Gymnema sylvestre* specified in applicants' claims would be useful or effective for treating each of these conditions.

It is urged that applicants' claims are novel and non-obvious in the manner required by 35 U.S.C. 102 and 103. Favorable reconsideration of the pending claims is respectfully requested.

Respectfully submitted,

By:   
Ann W. Speckman  
Registration No. 31,881

Date: May 13, 1999  
LAW OFFICES OF ANN W. SPECKMAN  
2601 Elliott Avenue, Suite 4185  
Seattle, Washington 98121  
Attention: Ann W. Speckman  
Telephone: (206) 269-0565  
Docket No. 53000/1001